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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,742	06/16/2000	Frederic J. de Sauvage	P1548R1	4676

9157 7590 01/09/2003

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/09/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,742

Applicant(s)

De Sauvage et al.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 28, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-20, and 22-27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 3, 22, and 23 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 7, 11-19, and 24-27 is/are rejected.
- 7) ☒ Claim(s) 6, 8, and 20 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Apr 3, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15 6) ☐ Other:

DETAILED ACTION

Status of Application: Claims and Amendments

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/12/02 has been entered.
2. Applicant is notified that the amendments put forth in Paper 14, 9/12/02, have been entered in full.
3. Claims 1-8, 11-20, 22-27 are pending.
4. Applicant is notified that any outstanding rejection or objection, that is not expressly maintained in this Office action, has been withdrawn.
5. Applicant is notified that the indicated allowability of claims 25-27 in Paper 12, 6/17/02, was erroneous, new rejections of claims 25-27 are indicated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4, 5, 7, 11-19, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as set forth because the specification, while being enabling for polynucleotides comprising a polynucleotide which encodes a polypeptide of having the amino acid sequence of SEQ ID NO: 2, or which encode polypeptides consisting of antigenic fragments of SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides that encode amino acid sequence variants of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As set forth previously, the issue is that the specification has failed to provide sufficient guidance to the highly skilled artisan to make variants of SEQ ID NO: 2 that have any particular function, and nor has the specification taught how to use the encompassed variants that have no particular function. Applicant does not appear to address this basis of the rejection.

7. Claims 1, 4, 5, 7, 11-19, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the claims have been amended to specify that the polypeptide of the subject claims bind to Gli. This argument has been fully considered but not deemed persuasive. The specification discloses a polynucleotide of SEQ ID NO: 1 encoding a polypeptide of SEQ ID NO: 2 that binds Gli, yet the claims encompass polynucleotides and polypeptides not described in the specification, e.g., sequences from other species, mutated sequences, allelic variants, anti-sense nucleic acid molecules, or sequences that have a recited degree of identity. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. Although one of skill in the art would reasonably predict that these sequences would or could exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polynucleotide sequence SEQ ID NO: 1 encoding a polypeptide that binds Gli. It is doubtful that this sequence is definitive of the claimed genus because the only related sequence, put forth in the specification, is *Drosophila* protein SEQ ID NO: 4 that is thought to bind Ci, but there is no indication that it binds Gli (see page 50 of the instant specification).

Thus, with the exception of the of the polynucleotide of SEQ ID NO: 1 and the polypeptide of SEQ ID NO: 2, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants. Therefore, only the following molecules, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph: (a) the polynucleotide of SEQ ID NO: 1, (b) the polypeptide of SEQ ID NO: 2, (c) polynucleotides that encode a polypeptide of SEQ ID NO: 2, (d) polynucleotides or polypeptides consisting of fragments of (a)-(c), and polynucleotides or polypeptides consisting of fragments as in (d) and heterologous nucleic acid or amino acids sequences (e.g. vector or tag sequences).

Conclusion:

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No: 6,448,020 discloses an isolated polypeptide that differs from the instant SEQ ID NO: 2 at one amino acid position, i.e. the instant SEQ ID NO: 2 has alanine at position 336 whereas proline occupies this position in 6,448,020-2.

Advisory information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael T Brannock whose telephone number is 703 306-5876. The examiner can normally be reached on Monday-Friday, 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703 308-6564. The fax phone numbers for the

Application/Control Number: 09/581,742
Art Unit: 1646

Page 6

organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

MB 
January 8, 2003


YVONNE EYLEY, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600